


## Case Report

# Walking ability following hybrid assistive limb treatment for a patient with chronic myelopathy after surgery for cervical ossification of the posterior longitudinal ligament

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**Context:** The hybrid assistive limb (HAL) (the wearable robot) can assist kinesis during voluntary control of hip and knee joint motion by detecting the wearer's bioelectric signals on the surface of their skin. The purpose of this study was to report on walking ability following the wearable robot treatment in a patient with chronic myelopathy after surgery for cervical ossification of the posterior longitudinal ligament (OPLL).

**Findings:** The patient was a 66-year-old woman with cervical OPLL who was able to ambulate independently with the aid of bilateral crutches. The wearable robot treatment was received once every 2 weeks for ten sessions beginning approximately 14 years after surgery. Improvements were observed in gait speed (BL 22.5; post 46.7 m/min), step length (BL 0.36; post 0.57 m), and cadence (BL 61.9; post 81.6 m/min) based on a 10-m walk test and a 2-minute walk test (BL 63.4; post 103.7 m) assessing total walking distance. The improvements in walking ability were maintained after the wearable robot treatment for 6 months.

**Conclusion:** We report the functional recovery in the walking ability of a patient with chronic cervical myelopathy following the wearable robot treatment, suggesting that as a rehabilitation tool, the wearable robot has the potential to effectively improve functional ambulation in chronic cervical myelopathy patients whose walking ability has plateaued, even many years after surgery.

**Keywords:** Hybrid assistive limb (HAL), Ossification of the posterior longitudinal ligament (OPLL), Chronic myelopathy, Wearable robot, Rehabilitation

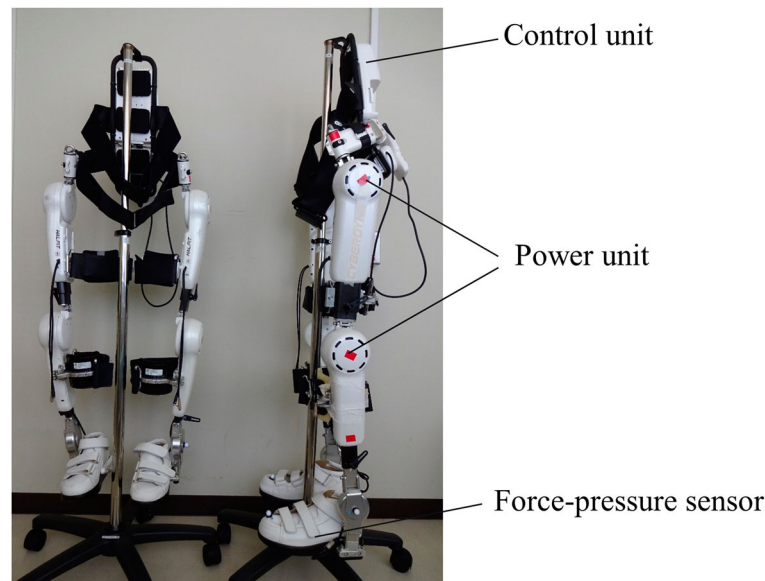
## Introduction

The hybrid assistive limb (HAL) (the wearable robot) can assist kinesis during voluntary control of hip and knee joint motion (Fig. 1). Motion is assisted via the detection of bioelectric signals, through an electrode on the anterior and posterior surface of the wearer's thigh and force-pressure sensors in the shoes, which

are processed through a computer.<sup>1</sup> The wearable robot has a hybrid control system comprised of cybernic voluntary control (CVC) and cybernic autonomous control (CAC) systems. The CVC mode of the wearable robot can support the patient's voluntary motion using voluntary muscle activity and the assistive torque provided to the hip and knee joint. The CAC mode can provide physical support autonomously, based on output from force-pressure sensors in the shoes. The feasibility and efficacy of the wearable robot has been shown in the functional recovery of multiple disorders in chronic<sup>2-4</sup> and subacute phases.<sup>5-7</sup>

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**Figure 1** The robot suit HAL®. The wearable robot has a power unit in the hip and knee joints on both lateral sides and force-pressure sensors in the shoes.

In the current case report, a patient who had a walking disorder in the chronic phase of myelopathy after surgery for cervical ossification of the posterior longitudinal ligament (OPLL) received wearable robot treatment. Three similar cases have been reported, but HAL treatment for those patients was provided in the early postoperative period.<sup>8–10</sup> Sakakima *et al.* reported that the walking ability of a thoracic OPLL patient, for whom the outcome of multiple surgeries did not facilitate ambulation, improved with HAL treatment.<sup>8</sup> We have reported that HAL treatment for a postoperative thoracic OPLL patient, in whom reagravation of paralysis occurred in the sitting position during the postoperative period, improved their walking ability.<sup>9</sup> Furthermore, we reported that HAL treatment, in surgically-treated thoracic OPLL patients with the inability to walk in the early postoperative phase, has the potential to effectively improve functional ambulation.<sup>10</sup> In the present case study, we report on improvements in walking ability following wearable robot treatment of a patient in the chronic phase of myelopathy after surgery for cervical OPLL.

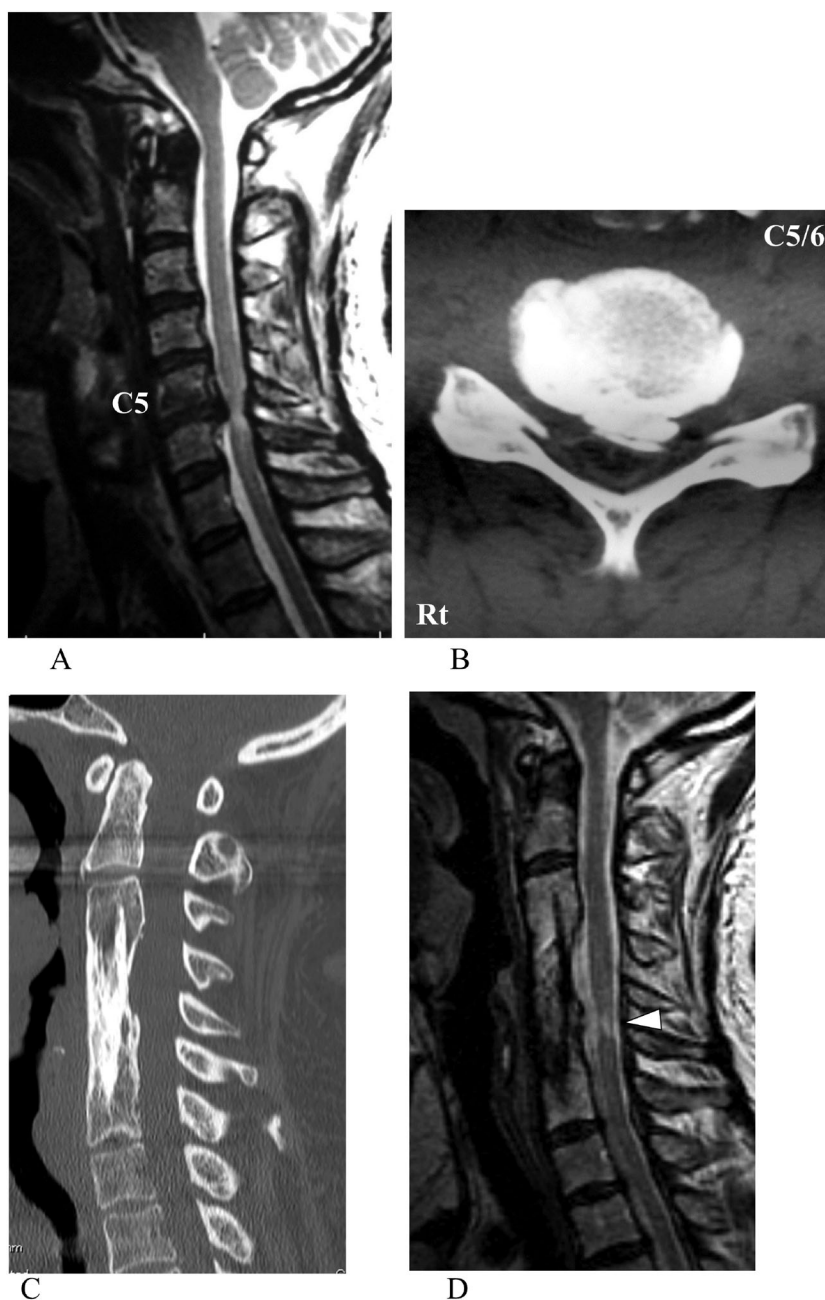
## Case report

### Patient

A 66-year-old woman, diagnosed with cervical myelopathy due to OPLL 14 years earlier underwent anterior decompression and spinal fusion surgery. Before surgery, her spinal cord was compressed anteriorly by cervical OPLL, and the most stenotic intervertebral level was C5/6 (Figs. 2A and 2B). The preoperative

Japanese Orthopaedic Association (JOA) score for cervical myelopathy was 8 out of a total score of 17 (8/17). Immediately after surgery, her myelopathy was slightly recovered and the JOA score increased to 9/17. Two years after surgery, the patient's myelopathy gradually worsened without any apparent cause and decreased to 8/17. Fourteen years after surgery, findings from magnetic resonance imaging (MRI) and computed tomography (CT) scans confirmed the compression of the spinal cord had resolved, but that spinal cord atrophy was present at the C5/6 level (Figs. 2B and 2C). Fourteen years after surgery, the patient wanted to undergo HAL treatment to attempt to improve her ability to walk.

Before wearable robot treatment, the patient scored 3 out of 6 on the bilateral manual muscle tests (MMTs),<sup>11</sup> indicating fair or full motion against gravity, of the iliopsoas, quadriceps femori, hamstring muscles, tibialis anterior, gastrocnemii, and wrist flexors, and scored 4 on the MMTs, good or full motion against gravity and some resistance, of the deltoids, biceps brachii, triceps brachii, and wrist extensors. Numbness in the right lower limb and in the left ulnar nerve was reported by the patient; however, her proprioception in both upper and lower extremities was found to be normal. Using the American Spinal Injury Association (ASIA) impairment scale (AIS),<sup>12</sup> a clinical evaluation showed the patient's grade was D on a scale ranging from grade E (least impaired) to grade A (most impaired). The patient's ASIA motor score (lower extremity) was 30 points (right, 15 points; left, 15 points) out of a total



**Figure 2** Imaging findings of the cervical spine before and after surgery. (A) Mid-sagittal section of a T2-weighted magnetic resonance image (MRI); (B) an axial section of a computed tomography (CT) myelogram at the C5/6 level before surgery, showing the OPLL that compressed the spinal cord anteriorly. (C) Mid-sagittal CT reconstruction and (D) mid-sagittal section of a T2-weighted MRI 14 years after surgery, showing that the spinal cord compression was resolved but atrophic changes of the spinal cord were present at the C5/6 level (arrowhead).

of 50 points and her ASIA sensory score for light touch was 101 points (right, 47 points; left, 54 points) out of a total 112 points. Based on the Frankel grading classification for spinal injuries on a scale ranging from grade A (complete neurological injury) to grade E (normal motor function), the patient was grade D. Using the Walking Index for Spinal Cord Injury (WISCI) II<sup>13</sup> scale ranging from 0 (inability to walk) to 20 (no walking devices, no braces, no assistance) the patient

scored 16 (ambulates with two crutches, no braces and no physical assistance, 10 meters), and using the Functional Independent Measure (FIM)<sup>14,15</sup> motor score based on ADL (activities of daily living), she scored 91 out of 91.

The patient was able to ambulate independently for approximately 300 m outdoors with the aid of bilateral crutches, and was able to walk indoors using props such as a wall or table for support. Although she did

not need supervision during walking with crutches, her gait was unstable and her steps were short. Without the aid of crutches, the patient was not able to ambulate independently due to the high risk of falling.

### *Functional evaluation*

A 10-m walk test and 2-minute walk test were conducted before the period of the wearable robot sessions had begun (baseline) and after it had finished (after training). Initial testing (base line) was performed on the day of the first wearable robot session before starting wearable robot treatment. The final test (after training) was performed on the day of post-evaluation, which was later than the day of the final wearable robot session. The primary outcome was the walking speed (m/minute) of the 10-m walking tests at the initial (baseline) and final (after training) evaluation. The 10 m walking speed and the walking time were measured using a hand-held stopwatch. In addition, the number of steps taken between the start and finish line were counted to calculate step length (m). Cadence was calculated based on the number of steps taken over the walking time and converted to steps/minute. During the 10-m walk test; the patient was instructed to walk without the wearing robot on a flat surface at a self-selected comfortable pace. During the 2-minute walk test, the patient was asked to walk for 2 minutes at her chosen maximal pace and the total distance walked was recorded. The 10-m walk test was also performed at each of the wearable robot sessions just before wearing the robot for an additional evaluation.

At every four sessions starting from the first wearable robot session; i.e. at sessions 1, 5 and 9, gait characteristics were measured using a VICON motion capture system (Vicon MX System with 16 T20s cameras; Oxford Metrics Ltd, Oxford, United Kingdom) three times during each of the three session: unassisted gait just prior to treatment with the robot (pre-robot); gait while ambulating with the wearable robot during treatment (robot); and unassisted gait after removal of wearable robot after treatment (post-robot). During these tests, the patient was instructed to walk on a flat surface at a self-selected comfortable pace. While walking with the wearable robot, the patient walked at a self-selected comfortable pace. Auto reflexive markers were attached on the feet following VICON plug-in gait marker placement on the foot; the head of the second metatarsal bone for the toe, lateral malleolus for the ankle and posterior peak of the calcaneus for the heel. Steps were extracted according to heel strikes detected as the lower peaks of the height of the heel markers. Toe lift was computed according to the relative

height displacement measured by maximum height minus minimum height of a toe marker for each step and then averaged among the extracted steps. Step length was computed for each step according to the horizontal distance between the position of a heel marker at the moment of a heel strike and the successive heel strike, and then averaged among the extracted steps. Toe lift and step length were computed first separately for the right and left sides and then averaged to obtain a representative value, because our focus was not lateral symmetry. Gait speed and cadence were also computed from the step data for pre-robot and post-robot in the same wearable robot treatment sessions (in the 1st, 5th, 9th sessions). Without the wearable robot the participant walked wearing her own comfortable shoes, and with the wearable robot she walked wearing the shoes of the robot. Since the evaluation of step detection, toe lift and step length depended on relative movement of a marker in each track, the slight differences in the heights of sole and toe cover between these shoes did not affect these evaluation.

### *Wearable robot treatment*

The device used for the research is equivalent to the marketed device that has been given the CE marking certificate (CE0197) for a medical device. In Japan, the device is approved as a medical treatment device used to delay the advancement of slowly progressive rare neuromuscular diseases.

Wearable robot treatment was started approximately 14 years after the patient underwent surgery for anterior decompression and spinal fusion. Upon initiation of the wearable robot treatment, the wearable robot was fitted and sitting and standing mobility was confirmed. The patient received wearable robot treatment once every 2 weeks for ten sessions (Fig. 3). To minimize the risk of falling for the patient, a walking device (AllinOne Walking Trainer; Healthcare Lifting Specialist, Denmark) with a harness was used. The CVC mode for the wearable robot was primarily used with the walking device and harness. Each wearable robot treatment session lasted 60 minutes and included the time taken for attaching/detaching the device, rest, single-leg motion, standing and sitting exercises, and walking on a 25-meter-long circuit several times with the assistance of two therapists and a doctor. One therapist operated the walking device and the other operated the computer. Net gait training time was approximately 15–20 minutes. The walking distance covered by the patient during wearable robot treatment sessions totaled approximately 2,100 m and averaged 210 m per session. Conventional physical therapy in the other



**Figure 3** Intervention by the wearable robot with a walking device and a harness for safety.

facilities, such as standing exercises and gait training with a walking device, was not performed concurrently with wearable robot treatment.

### Statistical analysis

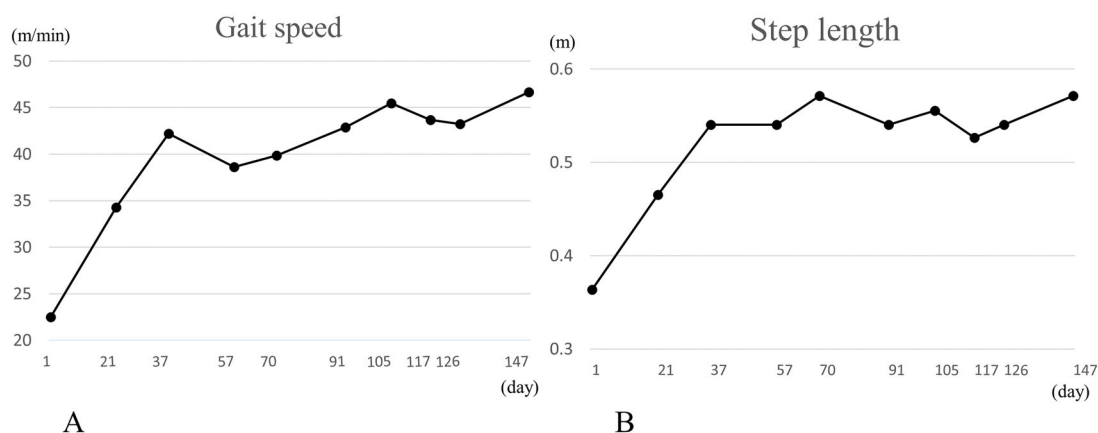
The toe lift and step length from data of the VICON motion capture system were analyzed by two-factor factorial ANOVA, and then differences among means were analyzed using Bonferroni/Dunn multiple comparison tests.

### Results

Improvements in gait speed, step length, and cadence for the 10-m walk test and the total walking distance covered in the 2-minute walk test were observed (Figs. 4A and 4B). The results of the 10-m walk test

and 2-minute walk test are shown (Table 1). Although the patient was not able to ambulate independently without the aid of crutches before wearable robot treatment, she was able to ambulate independently without them over a distance of at least 8 m after 10 sessions of wearable robot treatment. The gait speed in the 10-m walk test was 53.4 m/minute after wearable robot treatment for 6 months. Improvements in walking ability were maintained after wearable robot treatment.

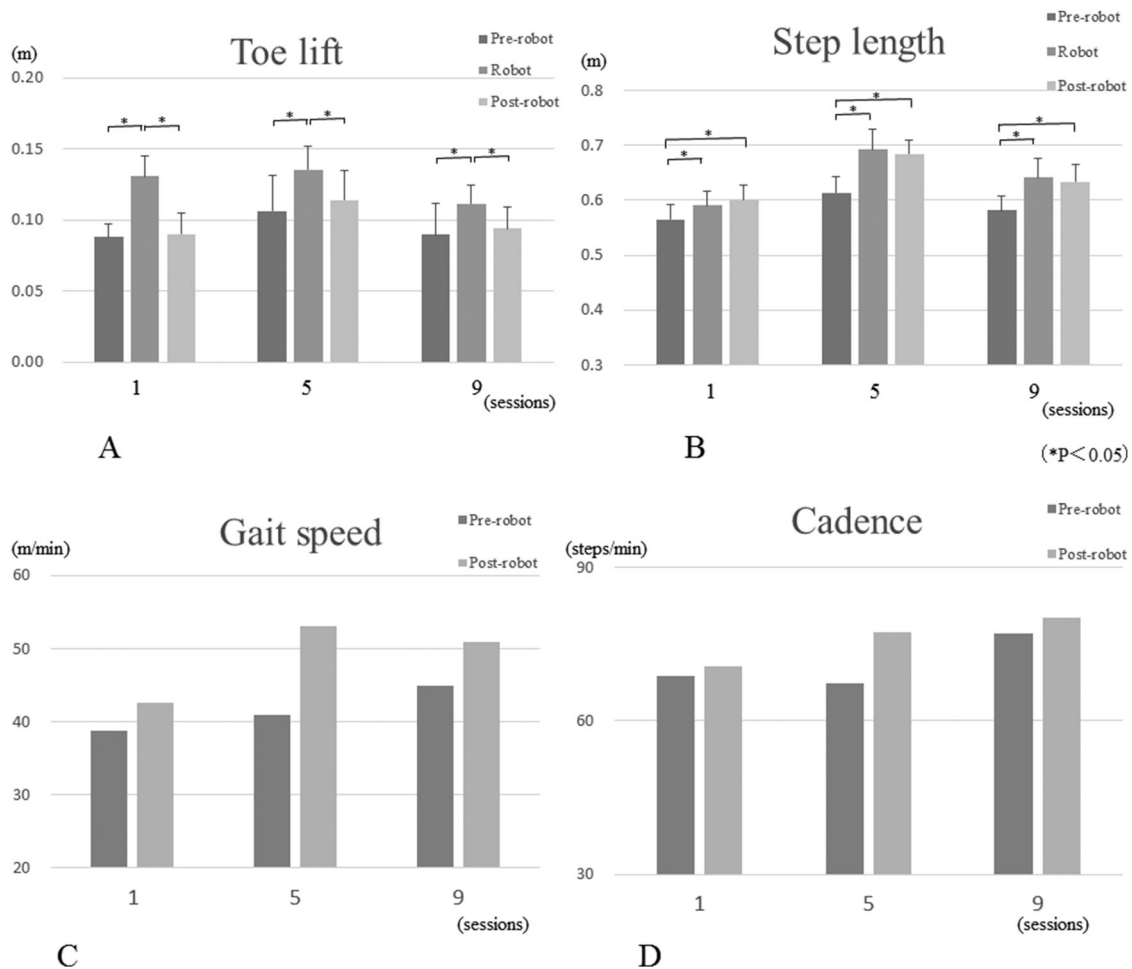
From the VICON data, the number of extracted steps were (24, 26, and 16), (38, 66, and 42) and (38, 18, and 42) for (pre-robot, robot, post-robot) for session 1, 5, and 9. While wearing the robot, toe lift and step length increased walking compared with pre-robot walking during the 1st (by 4.3 cm and 2.5 cm respectively), 5th (by 2.9 cm and 7.9 cm), and 9th (by 2.2 cm and 6.0 cm) wearable robot treatment sessions. These immediate effects persisted during walking after robot treatment, and were characterized by the increased toe lift and step length compared with the pre-robot phase in each of the 1st (by 0.2 cm and 3.5 cm), 5th (by 0.8 cm and 7.1 cm), and 9th (by 0.4 cm and 5.1 cm) sessions (Fig. 5A and B). Gait speed and cadence immediately increased from pre-robot to post-robot segments in the same wearable robot treatment session (Figs. 5C and 5D) and in subsequent sessions. Statistical analysis showed significant differences among the sessions ( $P < 0.05$  for toe lift, and  $P < 0.05$  for step length) and among the robot conditions ( $P < 0.05$  for toe lift and  $P < 0.05$  for step length). Interaction between the two factors was observed. Multiple comparison tests showed that toe lift was larger in Robot condition compared to Pre-robot ( $P < 0.05$ ) and to Post-robot ( $P < 0.05$ ) and step length was larger in Robot condition compared to Pre-robot ( $P < 0.05$ ) but not compared to Post-robot ( $P > 0.05$ ).



**Figure 4** Change in 10-m walk test without wearable robot. (A) Gait speed and (B) step length.

**Table 1** The results of the 10-m walk test, the 2-minute walk test, and the VICON motion capture system at baseline, after the training, and 1, 5, 9 session pre and post wearable robot treatment.

	10-m walk test			2-minute walk test Total walking distance (m)	VICON motion capture system			
	Speed (m/min)	Step length (m)	Cadence (steps/min)		Toe lift (m)	Step length (m)	Speed (m/min)	Cadence (steps/min)
At baseline	22.5	0.36	61.9	63.4	NA	NA	NA	NA
After the training	46.7	0.57	81.6	103.7	NA	NA	NA	NA
1th session pre-robot	NA	NA	NA	NA	0.09	0.57	38.7	68.6
1th session post-robot	NA	NA	NA	NA	0.09	0.60	42.7	70.6
5th session pre-robot	NA	NA	NA	NA	0.11	0.61	41.0	67.2
5th session post-robot	NA	NA	NA	NA	0.11	0.68	53.1	77.3
9th session pre-robot	NA	NA	NA	NA	0.09	0.58	45.0	77.0
9th session post-robot	NA	NA	NA	NA	0.09	0.63	50.9	80.2

**Figure 5** The results of the kinematic motion analysis using the Vicon motion capture system. (A) Toe lift, (B) step length, (C) gait speed, and (D) cadence.

**Table 2** The results of the ASIA motor score (lower extremity), ASIA sensory score, Frankel classification, WISCI II, and FIM motor score at baseline and after the wearable robot treatment.

	ASIA motor score (lower extremity)	ASIA sensory score	Frankel classification	WISCI II	FIM motor score
At baseline	15 / 15	47 / 54	D	16	91
After the training	18 / 16	47 / 54	D	16	91

The clinical evaluation, performed after the patient's final wearable robot treatment session, revealed the following results: (i) cervical JOA score was 9/17, (ii) AIS was grade D, (iii) ASIA motor score (lower extremity) was 34 points (right: 18 points, left: 16 points), (iv) ASIA sensory score for light touch was 101 points (right: 47 points, left: 54 points), (v) the Frankel classification was grade D, (vi) WISCI II was 16, and (vii) the FIM motor score was 91 (Table 2). This study was conducted with the approval of the Ethics Committee of the Tsukuba University Faculty of Medicine. This study was registered with the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN000014336).

## Discussion

We have presented a case of chronic cervical myelopathy with OPLL pathology in which an improvement in walking ability was achieved following 10 wearable robot physical therapy sessions, even after her walking ability had plateaued for approximately 14 years after surgery. The gait speed post-robot was faster than it was pre-robot (Fig. 5C). We had the impression that the gait speed while wearing the robot was fairly equal to that pre-robot. Therefore, it is difficult to believe that the patient immediately learned a faster gait while wearing the robot. However, because the patient could walk repeatedly with longer step and higher toe lift with the aid of the wearable robot (Figs. 5A and 5B) without the risk of falling, we consider that gait stability might have been improved and led to the faster gait post-robot.

Some of the measurements such as toe lift regressed closer to baseline during the 9th session compared to the 5th session (Fig. 5B). This might have arisen from the assist configuration of HAL in each of the sessions. At the earlier sessions, treatment was configured so that the patient could walk safely using a reciprocal bipedal gait, therefore with larger assistance in flexing of the hip and knee to achieve a higher toe lift. In the middle sessions, treatment was configured to achieve a longer swing motion with longer step, therefore, with increased assistance in the extension motion of the hip and knee. Among the measured sessions, the largest enhancement of step length was observed in the 5th session. Toward

the later sessions, assisted configuration was gradually reduced so that the patient could practice walking, gradually increasing reliance on her own ability, smoothness and efficiency while maintaining stability. By this reasoning, the amount of gait change influenced by HAL was considered to gradually decrease toward the later sessions.

Regarding improvement in gait speed and step length after 3 sessions start to plateau, we conjectured as follows. Our patient had a gait posture that was highly influenced by bilateral crutches. However, the gait of the patient changed quickly to a new gait posture during treatment by wearing the robot (longer step, higher toe lift). Therefore, improvement of gait speed and step length were observed especially in early sessions (from session 1 to 3). Later, because the patient became accustomed to her gait posture after wearing the robot after 4 sessions, we consider that the increase of gait speed and step length might have quickly plateaued.

Statistical analysis indicated that the toe lift and the step length significantly increased in the gait with Robot compared to the gait of Pre-robot (Figs. 5A and 5B). It shows that the assisted gait can be characterized by larger foot motion during swing phase. Statistical analysis also indicated that the gait changed significantly in the 5th session compared to the 1st session, and in the 9th session compared to the 5th session, in terms of the toe height and the step length (Figs. 5A and 5B). This might correspond to the above observation for the gait changes of the earlier sessions due to the removal of the crutches and of the later sessions due to the increased reliance on her own walking ability for smoother and more efficient gait. The removal of the crutches contributed to the increase of walking speed while the later changes did not, and therefore the plateau after the 3rd session (Figs. 4A and 4B). The limitation of the statistical analysis has to be noted since, first, there was only one participant in the experiments and, second, the effect of interaction between the session and the robot factors were large.

There have been several reports on robotic physical therapy for patients with chronic spinal cord injury (SCI).<sup>4,16,17</sup> Wirz *et al.* reported that after the robotic-assisted, bodyweight-supported treadmill training with

Lokomat three to five times a week, the 10-m walk test gait speed of 20 patients with a chronic motor incomplete SCI increased by  $0.11 \pm 0.10$  m/s.<sup>16</sup> Labruière *et al.* compared a robot-assisted gait training (RAGT) group with a strength training group of patients with chronic incomplete SCIs, and reported that mean gait speed improved from 0.62 m/second (37.2 m/minute) to 0.66 m/second (39.6 m/minute) in the RAGT group.<sup>17</sup> Improvement of the gait speed for our case (from 22.5 m/minute to 46.7 m/minute) was higher than the improvement (from 37.2 m/minute to 39.6 m/minute) of Labruière *et al.* The gait speed of our patient at baseline (22.5 m/minute) was lower than the gait speed of 9 patients of Labruière *et al.* at baseline (37.2 m/minute). For that reason, we considered that our patient might be easily influenced by gait training including conventional gait training. Therefore, the improvement of gait speed in our patient was higher than that of subjects in the study by Labruière *et al.* Aach *et al.* showed that the HAL physical therapy, performed five times per week over 90 days, significantly improved walking ability for eight patients with chronic SCI.<sup>4</sup> In particular, the mean ( $\pm$  standard deviation) total walking distance covered during a 6-minute walk test significantly improved from  $70.1 \pm 130$  m to  $163.3 \pm 160.6$  m. Our case also demonstrated that significant improvements in total walking distance occurred during a 2-minute walk test, despite the comparatively reduced frequency of wearable robot physical therapy sessions (once every 2 weeks).

We speculate that the effectiveness of motor learning in relation to walking ability improvements induced by wearable robot treatment is based on the patient's voluntary control. Wu *et al.* reported that locomotor training using a cable-driven robotic locomotor support system improved the walking speed and balance in ten patients with chronic incomplete SCI.<sup>18</sup> Because the cable-driven robotic locomotor system constrains leg movement and allows for variability in leg kinematics during treadmill walking, assistive training is important in motor learning. On the other hand, our wearable robot treatment could induce in real-time voluntary assistive motion via the wearer's voluntary signals (i.e. bioelectrical signals). We consider that sensory feedback was enhanced during walking while wearing the wearable robot because of real-time voluntary assistive motion that promoted superior motor learning effects. We conjectured that the mechanism underpinning the recovery of functional ambulation in this case was based on changes in plasticity of the spinal cord and supraspinal centers by the wearable robot-induced motion, which can facilitate favorable feedback effects.

Further studies are needed to compare the effectiveness of wearable robot treatment and conventional rehabilitation. We consider that the development of training programs according to the indicative disease and a term of disease for wearable robot treatment is necessary. An investigation of the difference in improvement between high-frequency training and low-frequency training with our wearable robot treatment is currently underway. Future studies also should examine the influence of the severity of spinal myelopathy and incomplete spinal cord injury on the effectiveness of wearable robot treatment.

### Study limitations

This case study has some limitations. First, this case study could not compare the efficacy of pure wearable robot treatment with conventional rehabilitation (gait training). Second, long-term efficacy of the wearable robot treatment could not be assessed. Third, this case study could not exclude observer bias because the same staff implemented evaluation and treatment.

### Conclusion

The wearable robot treatment for chronic cervical OPLL has the potential to improve the ability of a patient to walk, even years after surgery when their walking ability appears to have plateaued. More patients will be needed to evaluate the isolated effects of wearable robot treatment.

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### Conflicts of Interest

None.

### Contributor Statement

A commercial party having a direct financial interest in the results of the research supporting this article has conferred or will confer a financial benefit on 1 or more of the authors. Yoshiyuki Sankai is CEO of Cyberdyne Inc, Ibaraki, Japan. Hiroaki Kawamoto is a stockholder of the Cyberdyne. Cyberdyne is the manufacturer of the robot suit HAL. This study was proposed by the authors. Cyberdyne was not directly involved in the study design, the collection, analysis, or interpretation of data, writing the report, or the decision to submit the paper for publication. No commercial party having a direct financial interest in the


results of the research supporting this article has or will confer a benefit on the authors (Shigeki Kubota, Tetsuya Abe, Hideki Kadone, Kengo Fujii, Aiki Marushima, Tomoyuki Ueno, Yukiyo Shimizu, Yasushi Hada, Akira Matsumura, and Masashi Yamazaki) or on any organization with which the authors are associated.

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